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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,523	11/07/2001	Jiri Snaidr	235.017US1	9919
21186	7590	06/09/2004	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			SAKELARIS, SALLY A	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

10/008,523

Applicant(s)

SNAIDR, JIRI

Examiner

Sally A Sakelaris

Art Unit

1634

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 May 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.  
2. ☒ The proposed amendment(s) will not be entered because:  
(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ they raise the issue of new matter (see Note below);  
(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.  
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.  
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-24 and 28.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.  
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.  
10. ☐ Other: \_\_\_\_\_

  
CARLA J. MYERS  
PRIMARY EXAMINER

Continuation of 2. NOTE: The proposed amendment extensively modifies the claims and as a result will not be entered. The newly added recitations of separation solution temperatures, and separation solution contents in claims 1 and 28 and the new claims' recitation of a centrifugation separation step all include new limitations that require a new search of the prior art.

Continuation of 5. does NOT place the application in condition for allowance because: While Applicant submits that WO 99/18234 is not available as a reference under 35 U.S.C. §102(b), the rejection is maintained as applicant's claim to foreign priority has not yet been granted. Applicant further traverses this rejection on the grounds that the Guillot et al. reference teaches that "the preferred denaturing agent is formamide" and that "Guillot et al. provide an explicit teaching to use formamide as a denaturing agent, and do not provide alternatives for formamide or disclose disadvantages associated with the use of formamide" (Applicant's Response Pg. 8). This argument is not convincing as on page 8 lines 5-9 of the reference, WO 99/18234 asserts that the extraction of the probes can occur "in the presence of a probe-target denaturing agent such as one that will separate duplex DNA/DNA or DNA /RNA". The examiner maintains that in the absence of any evidence to the contrary, it is a property of any method in which the formamide is omitted that such a method allows for the detection of more detectable separated nucleic acid probe molecules than corresponding hybridized nucleic acid molecules. Furthermore, the claims are not limited to special conditions lacking formamide, i.e., conditions without formamide but with the specific inclusion of other reagents/conditions. The claim requires only the absence of formamide. The specification has not taught any particular conditions that must be used in combination with the absence of formamide to achieve the result of providing more detectable separated probe molecules than corresponding hybridized nucleic acid molecules. Applicant's traversal of the rejection under 103(a) concerning Guillot et al. reference is responded to above, in response to the standing 102(b) rejection. Applicant's arguments concerning the Roe et al. reference include the assertion that the reference "does not disclose or suggest whether the solutions disclosed therein are suitable for use in a method of detecting nucleic acids fixed microorganisms". Concerning the Kemp et al. reference, applicant asserts that the reference "does not teach or suggest a method of detecting the nucleic acid of fixed microorganisms in a sample" (Pg. 10 response). With respect to the above rejection over Guillot et al., Roe et al., and Kemp et al., applicant asserts that Roe et al. and Kemp et al. do not remedy the deficiencies of Guillot et al. and that neither Roe et al. or Kemp et al. provides one skilled in the art with a reasonable expectation that the instantly claimed methods of detecting microorganisms in a sample could have been carried out. Applicant asserts that that Sanders et al. do not remedy the deficiencies of Guillot et al. as neither Guillot et al. or Sanders et al. teach a method in which hybridized nucleic acid probes are separated without using formamide under conditions that provide more detectable separated nucleic acid probe molecules than corresponding hybridized nucleic acid molecules separated using formamide. However, the examiner maintains the rejection on the grounds that the claims are not limited to special conditions including both the absence of formamide and the inclusion of other reagents. As such the art as cited, obviates the above claims. Lastly, applicant asserts that the examiner omitted a suggestion or motivation to combine these above references and further that there is no motivation to combine the cited documents because they come from non-analogous art. However, the examiner finds these arguments to be unconvincing and maintains the rejection and points applicant to the last paragraph in the rejection where the expected benefit and motivation for combining the references can be found. The examiner also maintains that each of these references concern the same subject matter classified in Class 435 subclass 6 and as a result, steps of optimization, as discussed in MPEP2144.05(b), "(w)here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Aller, 220 F.2d 454,456, 105 USPQ 233,235 (CCPA 1955).

In addition, the declaration filed has not been entered and has not been considered because applicants have not provided a showing of "good and sufficient reasons" as to why the declaration was not presented earlier (See § 1.195 Affidavits or declarations after appeal). Furthermore, the remaining rejections are also maintained for reasons of record in view of the non-entry of after final amendment.